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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,110	04/21/2005	Michael R. Johnson	271083US96PCT	5374

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EXAMINER	
MURRAY, JEFFREY H	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
01/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/532,110	JOHNSON, MICHAEL R.	
	Examiner	Art Unit	
	JEFFREY H. MURRAY	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *209-384,389 and 395-397* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *09-384, 389, 395-397* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I.	The compound or composition of the formula I, where X=Cl, Y=NH_2, R^1 and R^2=H, according to Claims 209-296, 333-384, 389, and 395-397.
II.	The compound or composition of the formula I, not described by Group I, according to Claims 209-296, 333-384, 389, and 395-397.
III-IV.	The method of promoting hydration administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 297.
V-VI.	The method of restoring mucosal defense administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 298.
VII-VIII.	The method of blocking sodium channels administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 299.
IX-X.	The method of treating chronic bronchitis administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 300.
XI-XII.	The method of treating cystic fibrosis administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 301.
XIII-XIV.	The method of treating sinusitis administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 302.
XV-XVI.	The method of treating vaginal dryness administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 303.

XVII-XVIII. The method of treating dry eye administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 304.

XIX-XX. The method of promoting ocular hydration administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 305.

XXI-XXII. The method of promoting corneal hydration administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 306.

XXIII-XXIV. The method of promoting mucas clearance administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 307.

XXV-XXVI The method of treating Sjogren's disease administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 308.

XXVII- The method of treating distal intestinal obstruction syndrome
XXVIII administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 309.

XXIX-XXX. The method of treating dry skin administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 310.

XXXI- The method of treating esophagitis administering an effective
XXXII amount of a compound of Claim 209 as in ny of the Groups above, according to Claim 311.

XXXIII- The method of treating dry mouth administering an effective amount
XXXIV of a compound of Claim 209 as in any of the Groups above, according to Claim 312.

XXXV- The method of treating nasal dehydration administering an effective
XXXVI amount of a compound of Claim 209 as in any of the Groups above, according to Claim 313-314.

XXXVII- The method of preventing ventilator-induced pneumonia
XXXVIII administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 315.

XXXIX- The method of treating asthma administering an effective amount of
XL a compound of Claim 209 as in any of the Groups above, according to Claim 316.

XLI-XLII	The method of treating primary ciliary dyskinesea administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 317.
XLIII-XLIV.	The method of treating otitis media administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 318.
XLV-XLVI.	The method of inducing sputum administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 319.
XLVII-XLVIII	The method of treating chronic obstructive pulmonary disease administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 320.
XLIX-L.	The method of treating emphysema administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 321 and 324.
LI-LII.	The method of treating pneumonia administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 322.
LIII-LIV.	The method of treating constipation administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 323.
LV-LVI.	The method of treating chronic diverticulits administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 325.
LVII-LVIII.	The method of treating rhinosinusitis administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 326.
LIX-LX.	The method of treating hypertension administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 327.
LXI-LXII.	The method of reducing blood pressure administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 328.
LXIII-LXIV.	The method of treating edema administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 329.
LXV-LXVI.	The method of promoting diuresis administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 330.

LXIX-LXX. The method of promoting natriuresis administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 331.

LXXI-LXXII. The method of promoting saluresis administering an effective amount of a compound of Claim 209 as in any of the Groups above, according to Claim 332.

2. The inventions listed as Groups I - LXXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the claims is a compound of general formula I. Prior art exists which causes the core structure in the current application to lack a special technical feature. The core structure here is a pyrazine-2-carboxamide core. This ring is seen in numerous patents and papers. For example, Cantiello, et. al., Journal of Biological Chemistry (1989), 264(27), pp.16004, teaches a 3,5-diamino-N-carbamimidoyl-6-chloropyrazine-2-carboxamide named AMILORIDE where X is Cl, Y is NH_2, and R^1, R^2, R^3, and R^4 are hydrogen. Therefore, the feature linking the claims does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the art.

Accordingly, Groups I – LXXII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Examiner, Art Unit 1624

James O. Wilson
Supervisory Patent Examiner
Art Unit 1624